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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P-0020	5717

7590 07/03/2002
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EXAMINER

YOUNG, MICAH PAUL

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,304

Applicant(s)

RINGEISEN, TIMOTHY

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1 – 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al (USPN 5939323) in view of Fox Jr. et al, (USPN 5019096) both in further view of Tu et al (USPN 5024671). The claims are drawn to a process for making a porous polymeric material. The process comprises dissolving a polymer with a solvent, making a solution; adding another solvent to the solution; shaping the composition, and removing the solvents. The claims further recite that the process further comprises the addition of a biologically active agent, at varying time during the process. The claims also recite that a three-dimensional object is either used as a spreading surface or is forced into a volume of the composition (gel). This three-dimensional object is removed after the solvents are removed. The claims further recite specifically what polymer and which solvents are useful in carrying out this invention. Claims 15 – 25 are drawn

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to a process of making a composite body comprising the porous material. These of claims stipulate that the other material attached to the composition be biodegradable, and act as reinforcement to the compound. They recite that the limitation that the composite body is a component of a larger body.

4. Valentini et al discloses essential elements of the claimed invention. The reference teaches the formation of a porous scaffold material capable of acting as a substrate for various biologically effective agents. The scaffold is produced by first dissolving a solution comprising a polymer and a pore-forming agent with a solvent. The resulting solution is then combined with a second solvent, the first solvent is removed and pores are formed. The scaffold is capable of holding a wide variety of agents within its pores, from antibacterial agents to cells to proteins. The scaffold of the invention could be molded and shaped according to the needs of a skilled artisan in the field. The scaffold can also be attached to other bodies including other polymeric materials (col. 2, lin. 7 – 35; col. 6, lin. 38; examples). Though the reference does not disclose the polymeric material being dissolved of applicant, the general teaching of dissolving a polymer in a solvent and further adding another solvent is still present. Also the reference does not disclose the same solvents of applicant but again, the general teaching of dissolving a polymer in a solvent is present.

5. Fox Jr. et al discloses essential elements of claims 1, 2, and 7 – 12. The reference teaches an infection resistant coating for various surfaces. Fox discloses a method for producing this which includes dissolving a matrix-forming polymer in a solvent; dissolving an antimicrobial agent in a solvent; combining the two solutions; and allowing the resulting composition to dry (evaporation being the means of solvent removal). In one embodiment of the invention

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biomedical grade polyurethane is used as the polymer, and tetrahyrdofuran is used as the solvent. The coating of Fox can be used on sutures and other medical devices (col. 2, lin. 52 – 65, examples). Like Valentini, Fox does not disclose the second solvent of applicant, yet the general teaching of using two solvents is present. Also the teaching of the use of polyurethane and tetrahydrofuran (THF) is present in the reference. Another deficiency in the reference is that it does not disclose one of the objects that the compound is mechanically boned to. Fox teaches the bonding of the compound to sutures and other medical devices. The reference also teaches the coating of both metallic and plastic surfaces. Fox teaches the coating of surgical implants and devices, but not the tack of claim 22. Applicant provides no working examples showing a mechanical bond to a tack, nor does applicant place any criticality on the recitation in subsequent claims. It is the position of the examiner that barring a showing of criticality to the coating and inclusion of a tack as a composite material, the disclosure of metallic surgical implants is held obvious over the claim. Burden is shifted to applicant to provide said criticality to the coating and inclusion of a tack.

6. Tu et al teaches a vascular graft system. The reference discloses a component part coated with a porous polymeric material. The graft comprises a porous polymeric material attached to support fibers. The fibers are connected to each other via a polymer mixture solution of polyurethane in tetrahydrofuran. The reference discloses also that the graft can comprise reinforcing O-ring structures for support, and biodegradable materials for the release of active agents (Abstract; col. 6, lin.39 – 57; col. 7, lin. 20 – 23, 34 – 44). Though the coating of the reference comprises polyurethane and THF, Tu is silent to a second solvent used in the formulation.

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Despite the many teachings of Valentini, Fox, both references differ from the invention of applicant in a similar way. Also neither reference explicitly discloses the second solvent of applicant. Applicant claims the first solvent to be THF and the second to be chosen from the group chosen from p-dioxane, dimethyl sulfoxide and o-xylene. These compounds including THF are all well known (Nishijima USPN 3619250; col. 3, lin. 54 – 68) and would have been obvious to a skilled artisan for the purposes of making a porous polymeric material from polyurethane.

Another deficiency in the two references is their silence to the three-dimensional object as recited in claims 4 and 5. Valentine and Fox both describe methods of application, with Valentine teaching its molding process, yet both are silent as to the inclusion of a three-dimensional object. It is the position of the examiner that this process step is superfluous to the overall product of the process. Again the prior art presents similar process, and product, only differing in the inclusion of one element. Applicant provides no working examples utilizing the three-dimensional object nor does applicant place any criticality on its inclusion in subsequent claims. Burden is shifted to applicant to show the criticality of the inclusion of this process step. Barring this showing of criticality, all recitations of such an object cannot be given weight in the determination of the patentability of the application.

Another difference between the references and the claimed invention is the point at which the biological agent is added to the composition. Specifically claims 6 – 9, recite the agent being admixed into the composition with the first solvent, the second solvent or anytime before the solvents are removed. Applicant provides no working examples as to a difference in the result attained through changing the admixing point. It is the position of the examiner that the

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determination as to the point of the admixing could be determined by a person of ordinary skill in the art, and barring a showing of unexpected results, the differing mixing points cannot be seen as patentably distinct from the prior art disclosures.

With the teachings of the references taken into consideration, Valentino renders claims 1, 3, 6, 8 – 10, and 15, 23 and 24 obvious. Fox renders claims 1, 2, 6, 7, 10 – 15, 23, and 24 obvious, while Tu renders 11 and 15 – 25 obvious. One of ordinary skill in the art would have been motivated to combine the suggestions and teachings of the references. A skilled artisan would be motivated to follow the general teachings of Valentino to substitute polyurethane as the dissolved polymer, THF as a solvent (as seen in Fox), and any number of solvents recited by Nishijima et al in order to take advantage of polyurethane high bioavailability. A skilled artisan would have been motivated to combine this combination with the vascular graft of Tu, in order to not only bond the two fibrous components but to improve the bioavailability of the vascular implant. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings and suggestions in this way with an expected result of a porous polymeric material coated to a vascular graft, having improved bioavailability properties.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
June 27, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600